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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
APPLICATION FOR UNITED STATES LETTERS PATENT

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| TITLE: | USE OF A BREAST PUMP |
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USE OF A BREAST PUMP

This application is a Continuation-In-Part of U.S. Serial No. 10/401,138 filed March 27, 2003.

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FIELD OF THE INVENTION

The invention relates to a system and to a process for detecting a milk surge in a mother's breast and to the use of a breast pump for detecting a milk surge.

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BACKGROUND OF THE INVENTION

The human breast has mammary glands which form balloon-like structures, so-called alveoli. The alveoli are connected to one another via milk ducts which 15 lead to the nipple. The alveoli are enclosed by myoepithelial cells which contract under the influence of oxytocin. A sphincter at the end of the nipple, however, prevents the breast milk from flowing out.

If a baby then begins to suck at the breast, this is detected by mechanoreceptors 20 in the breast and a corresponding signal is transmitting to the mother's brain. Influenced by emotions, experiences and other external influences, the signal passes to the hypophysis which thus releases oxytocin.

The contraction of the myoepithelial cells triggered as a result leads to the alveoli 25 deflating, as a result of which the milk ducts are widened. If the nipple sphincter is then opened by pressure, heat or other external factors, the milk can flow out. This contraction is referred to as the milk surge.

The prior art discloses breast pumps which are likewise able to express milk from 30 the mother's breast. In particular WO 01/47577 discloses a milk pump which imitates the sucking rhythm of a baby and thus allows milk to be expressed from the breast in as natural a manner as possible.

Breast-feeding a baby, however, is not always straightforward. The causes of problems may stem from the baby or the mother or from both. It is often difficult, however, to determine the causes precisely. Expressing milk by means of a breast pump can also be problematic for some mothers. For the manufacturers of breast pumps, it is thus important to understand breast-feeding as precisely as possible and to utilize this knowledge in the design of breast pumps. It has been found that essential information for analyzing breast-feeding problems and for optimizing breast pumps may be derived from the mother's milk surge.

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10 It is another aspect of breast-feeding, that the volume of milk consumed by a baby is determined in order to make sure, that the baby is well fed. The simplest, however also a not very efficient way to do so is to weigh the baby before and after the feeding session.

15 US 5,827,191 therefore discloses a method for monitoring a volume of milk during breast feeding, the method utilizing an elastic nipple shaped cover applied over a nipple area of a woman's breast. The cover has holes positioned above the nipple area for passage of milk to the baby's mouth. A micro measurement volume sensor is located in a space between the nipple and the elastic cover holes to measure the

20 volume of milk flowing therethrough.

WO 01/54488 also discloses an apparatus for determining the amount of human milk supplied to a feeding baby during a breast-feeding session. A flowmeter is used to measure the milk supply.

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SUMMARY OF THE INVENTION

It is an object of the invention to provide a system and a process which allows a milk surge to be detected in a straightforward manner.

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This object is achieved by a system and a process having the features of patent claims 1 and 10, respectively.

It is another object of the invention to provide a system and a process which allows taking samples for milk analysis and/or individual use without interfering with a determination of the milk quantity.

- 5 This object is achieved by a system and a process having the features of patent claims 7 and 14, respectively.

In the process according to the invention, the milk is expressed into at least one collecting container and the quantity of milk expressed is determined as a function 10 of time. If a milk surge takes place, then the quantity of milk detected increases abruptly. It is thus easy to detect the milk surge.

The quantity of milk is preferably weighed. However, other determining methods, for example volume measurements, are also possible.

- 15 The change in the quantity of milk over time is preferably directly determined or calculated. This allows the point in time and also the intensity of the milk surge to be detected to better effect.
- 20 The measurement results and measurement curves obtained in this way can be evaluated, and it is possible to draw conclusions about the behavior of the corresponding test individual in response to various external and internal influences. Application areas for the system and process according to the invention are, for example, research, in order to obtain knowledge about the breast-feeding 25 behavior of babies and mothers. They may also be used, however, in hospitals or for advising mothers, in order to resolve breast-feeding or expressing problems. The results may also be used in product development, for the purpose of optimizing breast pumps.

- 30 In a variant of the process, the milk is collected in several containers, wherein the quantity of milk expressed is still determined as a function of time. If the quantity of milk is determined by weighing, the containers are preferably placed on the same balance. This enables splitting of milk collection whilst not interfering with

the continuous collection of weight data. Since the milk collection is split, the milk samples can be individually analyzed and/or used.

Further advantageous variants and embodiments can be gathered from the
5 dependent patent claims.

BRIEF DESCRIPTION OF THE DRAWINGS

The subject matter of the invention is explained hereinbelow with reference to
10 preferred exemplary embodiments illustrated in the attached drawing, in which:

Figure 1 shows a schematic illustration of the system according to the
invention;

15 Figure 2 shows a measurement curve obtained by means of the process
according to the invention and a calculated first derivative of the measurement
curve;

20 Figure 3 shows a schematic illustration of the system according to a second
embodiment of the invention and

Figure 4 shows a schematic illustration of the system according to a third
embodiment of the invention.

25 DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

The system of the invention according to Figure 1 has a breast pump 1, with at
least one breast shield 10 for expressing the milk from a human breast, at least one
30 collecting container 2, for receiving the milk expressed, and a unit with a
measuring means 3 and an evaluating means 4, by means of which a quantity of
milk received in the collecting container 2 is determined as a function of time.

The measuring means 3 serves for determining the weight or the change in weight of the breast milk located in the collecting container 2. In this preferred exemplary embodiment, this measuring means 3 is a balance, preferably an electromechanical balance with a bearing surface 30, on which the collecting container 2 is arranged.

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The balance 3 is electronically connected to the evaluating means 4, which is preferably a computing system, in particular a computer, in order to transmit the measured values from the balance 3 to the computer 4. It is also possible, however, for the computer 4 and balance 3 to be integrated in a single machine. The 10 measured values may be transmitted at defined time intervals or in a continuous manner.

In the evaluating means 4, the measured values and/or the change therein are illustrated as a function of time. Figure 2 illustrates a corresponding measurement 15 curve M and the derivative A thereof as a function of time. The y-axis shows the time in minutes, and the x-axis shows the mass in grams. The ovals O in figure 2 indicate the point in time of a milk surge. As can be seen, the flow of milk increases during a milk surge; the measurement curve M rises more rapidly. In the derivative A, the milk surges appear in the form of peaks and are thus even easier 20 to make out. It can also be seen from the two curves M, A that the milk surge need not always have the same intensity. These curves can be evaluated and the results used for a variety of different purposes mentioned above.

Figure 1 illustrates a table-top model of a breast pump. This means that the 25 pumping unit is arranged in a housing 11 and is connected, by means of a negative-pressure tube 12, to the breast shield 10, in order for the negative pressure which is necessary for the flow of milk to be achieved therein. The breast shield 10 is connected to the collecting container 2 via a connecting tube 13, with the result that the breast milk can pass through this tube 13 into the container 2, for example 30 a glass or a bottle. This apparatus has the advantage that the mother can move about during the test without falsifying the measurement result.

It is also possible, however, to use a breast pump in which the collecting container 2 is arranged on the breast shield 10. Here the important factor is for it to be possible to detect the behavior of the flow of milk over time.

5 Figure 3 shows a second embodiment of the invention. Instead of one single collecting container 2, several containers 2', 2'', 2''' are used. The containers 2', 2'', 2''' can have the same or different volumes. The number of containers 2', 2'', 2''' depends on the kind of analysis to be made. The three containers shown in figure 3 are therefore only an example. Preferably the containers 2', 2'', 2''' are
10 all connected to the same measuring means 3, which can be any of the measuring means mentioned above. In the example shown in figure 3, the measuring means 3 is again a balance, so that the containers 2', 2'', 2''' are placed on this balance 3.

15 The connecting tube 13 is preferably coupled with first moving means 14 for moving the tube 13 from a first to a second of said containers 2', 2'', 2'''. The tube 13 is moved to the next container 2', 2'', 2''' after a predetermined event. It is preferably moved automatically, the means being preferably controlled by the evaluating means 4. It is also possible to connect the evaluation means and the moving means to a separate, but common control means. This event is preferably a
20 time period passed, so that the connecting tube 13 is moved after a set time point. The time point can always be the same or it can change depending on the container to be filled. The event can also be a predetermined quantity of milk collected in one of the containers 2', 2'', 2''' or it can be something else.

25 The milk collected in the several containers 2', 2'', 2''' can be analyzed and also used individually. For example, as milk is removed from the breast the fat content of the milk increases and this system allows to track that increase.

30 This technique is extremely beneficial for mothers of premature infants for whom the energy density of milk is very important. The fat is responsible for approximately 50% of the energy in milk therefore, collecting the milk in fractions will provide volumes of milk with different energy densities. These can then be used individually or certain fractions can even be mixed to provide milk of specific energy density - an energy density best suited to the infant's needs.

Figure 4 shows third embodiment of the inventive system. Here, the measuring means 3, i.e. in this case the balance, is moved by second moving means 15 in order to fill the different containers 2', 2'', 2''''. This moving means 15, which can 5 for example be a motor-driven moving table, where the balance is being placed on, is preferably connected to the evaluation and control means 4.

List of designations

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| 1 | Breast pump |
| 10 | Breast shield |
| 11 | Housing |
| 12 | Negative-pressure tube |
| 13 | Connecting tube |
| 14 | moving means |
| 15 | second means |
| 2 | Collecting container |
| 2' | Collecting container |
| 2'' | Collecting container |
| 2''' | Collecting container |
| 3 | Measuring means |
| 30 | Bearing surface |
| 4 | Evaluating means |
| M | Measurement curve |
| A | Derivative |
| O | Oval |